

REMARKS

Claims 10-21 remain in this case and 10, 13, 16 and 21 are presented in amended form.

IN THE CLAIMS

Claims 10-21 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement by containing subject matter which is not described in the specification (See ¶2 of the Final Office Action dated 8/11/04). Claims 10-20 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite (See ¶4 of the Final Office Action dated 8/11/04). Applicant has made certain amendments to claims 10, 13, 16 and 21 in order to place all pending claims in this case in condition for allowance. Further, Applicant has provided argument below to support the case for allowance. Applicant respectfully requests that all pending claims be allowed.

A. Rejection under 35 U.S.C. § 112, first paragraph, is unfounded and should be withdrawn

Claims 10-21 stand rejected under 35 U.S.C. § 112, paragraph 1 as failing to comply with the written description requirement. Applicant respectfully traverses the rejection in its entirety. In particular, independent claims 10, 16 and 21 have been rejected based upon certain amendments to the claims in the November 21, 2003 response. The previous response added three particular claim limitations, stated in various ways in each independent claim, that the Final Office action rejects under 35 U.S.C. §112, first paragraph.

In particular, claim 10 was amended to add three specific limitations that form the basis for the §112, first paragraph rejection. The first limitation recites "a stack of receiving plates unconnected to and unconnectable to any other structure." The second limitation recites a "stack of receiving plates . . . having only a plurality of apertures formed therein each sized to receive a pipette tip therethrough." The third limitation recites a "transfer member configured to not be

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connectable to any receiving plate of said stack of receiving plates." Applicants will address the §112, first paragraph rejection for each claim limitation in separately titled sections hereunder.

Independent claims 10, 16 and 21 incorporate some or all of the three limitations listed above, in some shape or form. Since independent claim 10 incorporates all three limitations, claim 10 will be addressed at the outset. The arguments provided for claim 10 will also apply to similar limitations contained within independent claims 16 and 21. Any differences will be addressed separately thereafter.

1. **The previous amendment to independent claim 10 adding a limitation to recite that the claimed stack of receiving plates has "only a plurality of apertures formed therein each sized to receive a pipette tip therethrough" is not new matter.**

Applicant respectfully traverses the 35 U.S.C. §112, paragraph 1 rejection of claim 10 based on the addition of new matter - i.e. the addition by amendment to claim 10 of the limitation "having only a plurality of apertures formed therein each sized to receive a pipette tip therethrough." Notwithstanding the traverse by Applicant, Applicant amends claim 10 to remove the claim limitation "having only" and replaced it with the limitation "consisting of." The closed-ended transition term "consisting of" conveys what the Applicant intended with the amended phrase "having only," namely, that the receiving plates have a plurality of apertures formed therein each sized to receive a pipette tip therethrough, **and no other structure or element formed therein**. The original amendment was never intended to amend the claims so that the receiving plates have **only** a plurality of apertures, i.e. the number of apertures formed on the receiving plate must only be a plurality (emphasis added in the Final Office action).

"[I]nformation contained in any one of the specification, claims or drawings of the application as filed may be added to any other part of the application without introducing new matter." See MPEP §2163.06. Because the specification and drawings of the application as filed

support the amendment introducing the limitation "having only a plurality of apertures formed therein each sized to receive a pipette tip therethrough," Applicant asserts that no new matter was involved, and the rejection asserting the addition of new matter by amendment was groundless.

Even though it is improper to read the "having only" limitation as requiring only a plurality of apertures in number, Applicant first directs attention to specific references in the originally filed specification supporting the limitation "having only a plurality of apertures," as that claim limitation is being interpreted in the Final Office action. At the outset, it should be noted that one of the important objects of the present application is to minimize the amount space needed to store pipettes. In the Brief Summary of the Invention, the Applicants recite that "[t]he present invention relates to a new and improved pipette tip packaging and transfer system which takes up a small amount of space so as to minimize the amount of packaging and materials produced." See Application as filed, lines 20-23.

During prosecution, the Office cannot interpret a claim limitation so as to render the system inoperable. If the claim interpretation offered in the Final Office action were adopted, and a stacking plate were to have anything less than a plurality of apertures for a plurality of pipette tips (i.e. one aperture for one pipette), the number of stacking plates required to practice Applicants' transfer system would be ridiculous. The amount of space required for storing the pipettes would not just double or triple, but increase exponentially.

Applicant directs attention to further discussions within the specification supporting a stacking plate having nothing less than a plurality of apertures for pipettes. For example, FIG. 1 shows a receiving plate 20 having a plurality of openings 22. See Application as filed, FIG. 1. Consistent with FIG. 1, in the specification, the Applicant discusses that each receiving plate 20 includes a rectangular array of ninety-six (96) openings 22 for receiving pipette tips 26, which is

also illustrated in FIG. 2. See Application as filed, page 6, lines 13-15 and FIG. 2. Moreover, the Applicant also illustrates a holder tray 78 which is typically configured to hold 96 pipette tips. See Application as filed, lines 25-26. Throughout the specification, the Applicant refers to more than a single pipette tip contained within the receiving plate, necessitating the need for a plurality of apertures and no less.

In support of the §112, paragraph 1 rejection, the Office Action refers to a portion of Applicants' specification where it is stated that "it is understood that receiving plate 20 can include any number of openings 22." One skilled in the art would recognize, based upon the foregoing discussion, that the recitation of "any number of openings 22" does not mean anything less than a plurality. Such recognition would follow from, among other things, (i) the Applicants' Brief Summary of the Invention (See Application as filed, page 3, lines 20-24, lines 26-28); (ii) the detailed description of the preferred embodiment (See Application as filed, page 6, lines 13-15, lines 16-17; page 8, lines 5-16; page 9, lines 24-26); (iii) the information conveyed in FIGS. 1, 2, 4, 7 and 8; and (iv) the positive recitation in the originally filed claim 1 of a stacking plate having nothing less than a plurality of apertures (See Application as filed, independent claim 1, "a receiving plate having a plurality of apertures sized for and having pipettes positioned therethrough").

In summary, nowhere in the specification, claims or drawings as filed does Applicant suggest the possibility of having a stack of receiving plates with anything less than a plurality of apertures. Rather, Applicant discloses a transfer system having only a plurality of apertures for receiving a plurality of pipette tips. This characterization of Applicants' disclosure is consistent with a primary objective of Applicants' transfer system, which is the reduction of space for a stack of receiving plates - i.e. receiving plates having more than a single aperture for a single

pipette. Accordingly, the Applicants respectfully disagree with the contention that the addition of the limitation "only a plurality of apertures formed therein each sized to receive a pipette tip therethrough" to claim 10 constitutes new matter. Applicant requests reconsideration of the rejection.

Since the limitation "having only" is supported by the original specification, claims and figures, amended claim 10 adding the limitation "consisting of" is supported as well. Because claim 10 as amended is clearly supported by the specification, Applicant requests that the rejection under 35 U.S.C. §112, paragraph 1 be withdrawn.

2. **The previous amendment to independent claim 10 adding a limitation to recite that the claimed stack of receiving plates is "unconnected to and unconnectable to any other structure" is not new matter.**

Applicant respectfully traverses the 35 U.S.C. §112 rejection of claim 10 based on the addition of new matter - i.e. the addition by amendment to claim 10 of the limitation "a stack of receiving plates unconnected to and unconnectable to any other structure" (emphasis added to show the amended limitation). Notwithstanding the traverse by Applicant, Applicant amends claim 10 to remove the claim limitation "any other structure" and replaced it with the limitation "a transfer member." The currently amended phrase "a stack of receiving plates unconnected to and unconnectable to a transfer member" conveys what the Applicant intended with the phrase "a stack of receiving plates unconnected to and unconnectable to any other structure," that is, that the receiving plates are not connected to and cannot be connected to any other structure, specifically, a transfer member that maintains pipette tips in a substantially vertical orientation with respect to a receiving plate.

Because the specification and drawings of the application as filed support the original amendment introducing the limitation "unconnected to and unconnectable to any other structure," Applicant asserts that no new matter was involved, and the rejection asserting the

addition of new matter by amendment is groundless. The Applicant directs attention to specific references in the originally filed specification supporting the limitation "unconnected to and unconnectable to any other structure." For example, the discussion of the method discloses that "the transfer member is urged onto the uppermost receiving plate 20 of stack 66 by aligning projections 34 and engaging the same in the top opening 26 of each pipette tip 24 contained in the uppermost receiving plate 20." See Application as filed, page 10, lines 5-8. Continuing with the discussion, "with receiving plate 20 and transfer member 30 firmly grasped by the user between the thumb and forefinger. . ." See Application as filed, page 10, lines 11-12. Finally, the discussion of the method concludes by reciting that "[t]he user then releases the sides of receiving plate 20 and lifts transfer member 30 upwardly and away. . ." See Application as filed, lines 16-17.

Based upon the cited pages in the original specification, the receiving plate must be unconnected to any other structure (e.g. the transfer member) for the described method to operate. The two elements are necessarily unconnected, because the receiving plate and transfer member have to be firmly grasped between the thumb and the forefinger to lift the two elements up and away from the stack of plates. Moreover, once the user releases his/her firm grasp on the receiving plate, the transfer member can be lifted up and away because the projections of the transfer member are easily removed from the top openings of the pipettes in the apertures of the receiving plate. If there was a connection between the receiving plate and any other structure, this operation would not be possible.

The receiving plate is also unconnectable to any other structure, in addition to being unconnected to any other structure. The amended claim specifies receiving plates "consisting of a plurality of apertures formed therein each sized to receive a pipette tip therethrough. The

closed-ended transition term "consisting of" means that the claim element covers only receiving plate having a plurality of apertures for receiving a plurality of pipette, and no more and no less. Therefore, the receiving plate cannot have another element that would allow it to be connectable to any other structure, particularly the transfer member. So, it is necessarily unconnectable to any other structure.

The Applicant also directs attention to the fact that the transfer member and the receiving plate are never connected to one another and are unconnectable to one another because there is always an intervening element -- i.e. the pipettes -- between the transfer member and the receiving plate. The transfer member has projections or bosses for engaging the openings in the tops of the pipette tips. However, the projections on the transfer member are designed to snugly fit and engage the top opening of each pipette tip without "connecting" to the pipette tip. The pipettes are never connected to the transfer member. Similarly, the pipette's distill tips are sized to nestle into the apertures of the receiving plate, but are in no way "connected" to the apertures or the receiving plate itself. So, the pipette tips are neither connected to the receiving plate nor the transfer member. Therefore, the pipette tips are not connected to the receiving plate, the pipette tips are not connected to the transfer member, and there is no connection between the receiving plate and the transfer member using the pipette tips.

In support of the §112, paragraph 1 rejection, the Office Action refers to a portion of Applicants' specification where the plate is described as "... having a plurality of openings for receiving pipette tips in a substantially vertical alignment at a medial position thereof. The loaded receiving plates can be stacked one on top of another with the pipette tips contained within a receiving plate contained within a first receiving plate being received in the top openings of the aligned pipette tips contained within the underlying receiving plate of the

stack . . .” (See Applicants original application, page 3, line 27 - page 4, line 2). The cited passage actually supports the Applicants’ position. There is nothing in the cited passage that discloses the connection of a receiving plate to any other structure. The passage simply explains the stacking procedure for multiple receiving plates, which is more clearly described with reference to FIG. 4 . (See Application as filed, page 8, lines 3-19).

In summary, one skilled in the art would recognize, based upon the foregoing discussion, that the receiving plates are clearly unconnected and unconnectable to any structure, including the transfer plate. Such recognition would follow from, among other things, the specification, claims and drawings as filed showing that Applicant discloses a transfer system having a transfer member with projections or bosses that engage the top opening of each pipette tip for maintaining the pipette tip in substantially perpendicular alignment in relation to the transfer member and a receiving plate that only has a plurality of apertures for receiving pipette tips. The plate and transfer member are held in alignment by a user’s thumb and forefinger, and are in no way connected or connectable. This characterization of Applicants’ disclosure is consistent with another important objective of Applicants’ transfer system, which is a transfer system that is easy and simple to facilitate the transfer of pipette tips from a storage container to a holding tray without requiring a latching mechanism. Accordingly, the Applicants respectfully disagree with the contention that the addition of the limitation “unconnected to and unconnectable to any other structure” to claim 10 constitutes new matter. Applicant requests reconsideration of the rejection.

Because the limitation “unconnected to and unconnectable to any other structure” is supported by the original specification, claims and figures, the amended claims adding the limitation “unconnected to and unconnectable to a transfer member” (emphasis added) are

supported as well. Because claim 10 as amended are clearly supported by the specification, the rejection under 35 U.S.C. §112, paragraph 1 should be withdrawn.

3. **The previous amendment to independent claim 10 adding a limitation to recite that the claimed transfer member is "configured to not be connectable to any receiving plate of said stack of receiving plates" is not new matter.**

Applicant respectfully traverses the 35 U.S.C. §112 rejection of claim 10 based on the addition of new matter - i.e. the addition by amendment to claim 10 of the limitation a "transfer member configured to not be connectable to any receiving plate of said stack of receiving plates." (emphasis added to show amended limitation). For similar reasons that the limitation "a stack of receiving plates unconnected to and unconnectable to any other structure" is not new matter (as described above), the non-connectability aspect of the transfer member is also not new matter.

Because the specification and drawings of the application as filed support the original amendment introducing the limitation "configured to not be connectable to any receiving plate of said stack of receiving plates," Applicant asserts that no new matter was involved, and the rejection asserting the addition of new matter by amendment is groundless.

In particular, the transfer member is configured to engage the pipette tips nestled within the apertures of the receiving plates, but is not configured to connect to the receiving plates themselves. For example, the specification recites in several places that the projections or bosses of the transfer member are positioned to align them with the proximal ends of the pipette tips. (See Application as filed, page 7, lines 23-25; page 7, lines 26-28; page 8, lines 20-21; page 8, lines 25-27; page 8, lines 27-29; page 9, lines 4-6; page 9, lines 10-12). In the description of the method, the transfer member is "urged onto the uppermost receiving plate 20 of stack 60 by aligning projections 34 and engaging the same in the top opening of each pipette tip 24 contained

in the uppermost receiving plate 20.” (See Application as filed, page 10, lines 5-9). Since the thrust of the invention is the engagement of the transfer member with the pipette tips, there is no reason to configure the transfer member to connect to the receiving plate.

The not connectable aspect of the transfer member is further evidenced by the specification, claims and figures as originally filed, because none of them show or describe any manner of connecting the transfer member to any of the receiving plates. There is no reason to form the connection because the only function of the transfer member is to engage the pipette tips and maintain the pipette tips in a fixed and substantially perpendicular alignment in relation to the transfer member and the receiving plate. Therefore, the transfer member and the receiving plate would never be connected.

The description of the method in the specification and figures as originally filed reaffirms the unnecessary aspect of connecting the transfer member to the receiving plate. (See Application as filed, page 10, lines 5-21). In fact, a connection between the transfer member and the receiving plate defeats the operability of the method. Therefore, it is desirable for the transfer member to be configured to be not connectable to the receiving plate in order for the method to work as intended.

In support of the §112, paragraph 1 rejection, the Office Action refers to a portion of Applicants’ specification where the transfer member is described as “a flat rectangular plate having dimensions that substantially match those of receiving plate. A plurality of projections or bosses are attached to the bottom surface of the rectangular plate to extend away therefrom a distance selected to facilitate connection and stable alignment of the pipette tips . . .” (See Applicants original application, page 7, lines 11-25). The cited passage specifically states that the transfer member is designed to facilitate connection and stable alignment of the pipette tips.

There is nothing in the cited passage that discloses connecting the transfer member to the receiving plate. The passage simply explains the structure of the transfer member for engaging the pipette tips.

In summary, one skilled in the art would recognize, based upon the foregoing discussion, that the transfer member is clearly not connectable to any receiving plate in a stack of receiving plates. Such recognition would follow from, among other things, the specification, claims and drawings as filed showing that Applicant discloses a transfer system having a transfer member with projections or bosses that engage the top opening of each pipette tip for maintaining the pipette tip in substantially perpendicular alignment in relation to the transfer member. The plate and transfer member are held in alignment by a user's thumb and forefinger, and are in no way connectable. Accordingly, the Applicants respectfully disagree with the contention that the addition of the limitation "configured to not be connectable to any receiving plate of said stack of receiving plates" to claim 10 constitutes new matter. Applicant requests reconsideration of the rejection. Specifically, Applicant requests that the rejection of claim 10 under 35 U.S.C. §112, paragraph 1 be withdrawn.

4. Independent claims 16 and 21 contain amendments similar to independent claim 10 and are therefore not new matter for the same reasons.

Claim 16 recites the limitations "a receiving card unconnected to and configured to not be attachable to any structure configured for engaging and maintaining said pipette tips in a stable position relative to said receiving card" and "said transfer member being configured with no structure for attaching said transfer member to said receiving card." (emphasis added). Claim 21 recites the limitations "a receiving card consisting of a matrix of card apertures formed therein" and "said transfer member being without structure for connecting said transfer member to said receiving card." (emphasis added). For the reasons discussed above with respect to the

comparable limitations recited in claim 10, the amended claim limitations of claims 16 and 21 are clearly supported by the specification and do not comprise new matter. Applicant requests reconsideration of the rejection. Specifically, Applicant requests that the rejection under 35 U.S.C. § 112, paragraph 1 be withdrawn for claims 16 and 21.

B. Rejection under 35 U.S.C. § 112, second paragraph, is unfounded and should be withdrawn

Applicant respectfully traverses the Examiner's rejection of claims 10-20 for failure to particularly point out and distinctly claim the subject matter which Applicant regards as his invention - i.e. that the recitation in claim 10 that the receiving plates are "unconnected to and unconnectable to any other structure." Notwithstanding the traverse by Applicant, Applicant has amended claim 10 to remove the claim limitation "any other structure" and replaced it with the limitation "a transfer member." The currently amended phrase "a stack of receiving plates unconnected to and unconnectable to a transfer member" conveys what the Applicant intended with the phrase "a stack of receiving plates unconnected to and unconnectable to any other structure," namely, that the receiving plates are not connected to and cannot be connected to any other structure, specifically, a transfer member that maintains pipette tips in a substantially vertical orientation with respect to a receiving plate.

The second paragraph of 35 U.S.C. § 112 requires claims to set out and circumscribe a particular area with a reasonable degree of precision and particularity. In re Johnson, 558 F.2d 1008, 1015, 194 USPQ 187, 193 (CCPA 1977). In making this determination, the definiteness of the language employed in the claims must be analyzed, not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art. Id.

The focus of rejecting claims 10-20 is that the reference to "unconnected to and unconnectable to" is indefinite. In response, Applicant respectfully asserts that the rejection is not focusing on the claim language in light of the teachings of the prior art and of the disclosure contained in the Applicants' specification. In other words, when the claim language referencing "unconnected to and unconnectable to" is viewed in light of Applicants' specification, drawings, and claims in light of the prior art (e.g. U.S. Patent No. 5,324,482 to Scaramella et al.), the claims circumscribe the boundaries of the claimed subject matter with the requisite degree of precision and particularity.

As stated previously in this response, the receiving plate must be unconnected to other structure (e.g. the transfer member) for the method of the present invention to operate as intended. The two elements are necessarily unconnected, because the receiving plate and transfer member have to be firmly grasped between the thumb and the forefinger to lift the two elements up and away from the stack of receiving plates. Moreover, once the user releases his/her firm grasp on the receiving plate, the transfer member can be lifted up and away because the projections of the transfer member are easily removed from the top openings of the pipettes in the apertures of the receiving plate. If there was a connection between the receiving plate and any other structure, this critical operation would not be possible.

Also stated earlier in this response, the receiving plate is unconnectable to any other structure, in addition to being unconnected to any other structure. The amended claim specifically recites a stack of receiving plates "consisting of a plurality of apertures formed therein each sized to receive a pipette tip therethrough." The claim element covers receiving plates consisting of a plurality of apertures for receiving a plurality of pipette tips, and no more and no less. However, the receiving plates are not connected to or connectable to the pipette tips.

The pipette tips are merely placed into the apertures and held in position by the size of the opening. (See Application as filed, page 6, lines 20-24). Therefore, the receiving plate cannot and does not have an element that would allow it to be connectable to any other structure, particularly the transfer member. As a result, it is necessarily unconnectable to any other structure.

In addition, the prior art, and particularly Scaramella, teaches the use of a latching mechanism specially designed to releasably secure the holder card to the transfer plate to prevent relative rotation between the card and the plate. Applicant, on the other hand, discloses a system that enables the functions of the latching mechanism, without the need for any structure to make a connection between the transfer plate and holder card, particularly the latching mechanism element. Applicant has therefore disclosed and claimed a receiving plate that is unconnected to and unconnectable to any other structure, including a transfer member, that is an improvement over the prior art, including Scaramella.

Claim 16 recites the limitation "a receiving card unconnected to and configured to not be attachable to any structure configured for engaging and maintaining said pipette tips in a stable position relative to said receiving card." Claim 16 was amended to specify what structure the receiving card is "unconnected to and configured not to be attachable to." For the reasons discussed above with respect to the comparable limitations recited in claim 10, the amended claim limitation of claims 16 clearly particularly points out and distinctly claims the subject matter which Applicant regards as his invention.

As those skilled in the art will recognize, the dimensional boundaries of the claimed subject matter of Applicants' transfer system, using a receiving plate that is "unconnected to and unconnectable to" any other structure, the mandate of 35 U.S.C. §112, second paragraph, is

satisfied. Therefore, Applicant respectfully requests that the rejection be withdrawn for claims 10-20.

INVENTORSHIP

At paragraph 5 of the Office Action, the Examiner again discusses inventorship. Applicants are still confused by this discussion and the reference to 37 C.F.R. § 1.56 inasmuch as there is still no evidence, suggestion, discussion or indication in the record that any one or more of the identified inventors did not make the minimum inventive contribution to the disclosed and claimed inventions.

Applicants are aware of their duty to disclose. Be that as it may, the listed inventors were at the time of the invention all employees of MEDAX, Inc., the actual owner of the present application. Under 35 U.S.C. § 103 (c), if there was work of one inventor later advanced or undertaken by another inventor separate from the others at MEDAX, such work would not be regarded as prior art.

CONCLUSION

The rejection of claims 10-21 is deemed avoided. In turn, all claims should be allowable. Early action and allowance is respectfully requested for all pending claims. If there are questions, the Examiner can reach applicants' counsel at (801) 521-5800 or by e-mail at rossat@HRO.com.

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Respectfully submitted,

Thomas J. Rossa
Registration No. 26,799
Customer Number 34013
Attorney for Applicants
HOLME ROBERTS & OWEN LLP
299 South Main, Suite 1800
Salt Lake City, Utah 84111-5233
Telephone: (801) 521-5800

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